REMARKS

This paper responds to the Office Action dated April 6, 2011.

Claims 25 and 42 are amended, no claims are canceled, and no claims are added. Claims 32, 33, and 41 were previously cancelled. As a result, claims 25-31, 34-40, and 42 are now pending in this application.

Claims 25 and 42 are amended to recite that "at least one preselected portion of the coating is removed after contact with an aqueous environment and wherein the remaining portion of the coating is not removed. This amendment is grammatical in nature.

No new matter has been added with these amendments.

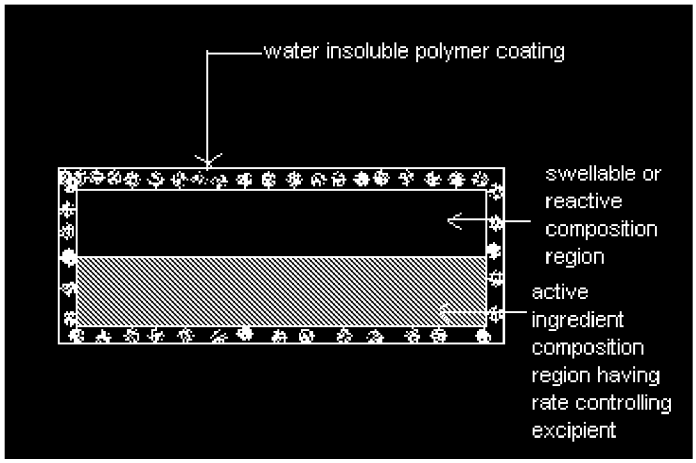
Applicants' Invention:

Before responding to the the Office Action, Applicants would like to summarize their invention.

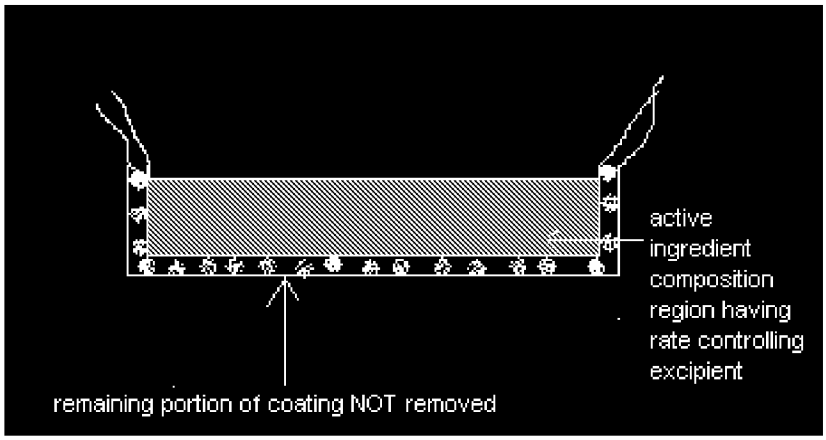
Applicants' orally administerable drug delivery system as presently claimed in independent claims 25 and 42, is illustrated in the following figures.

Upon contact with aqueous environment, at least one preselected portion of the coating is removed, and water enters into the swellable or reactive composition where it causes the swellable region to swell or the reactive region to react, and "blow off" only that portion of the insoluble polymer layer in contact with the swellable or reactive composition. As a result, as shown below, only the core portion of Applicants' orally administerable drug delivery system remains.

System as claimed in claims 25 and 42 before contact with an aqueous environment.



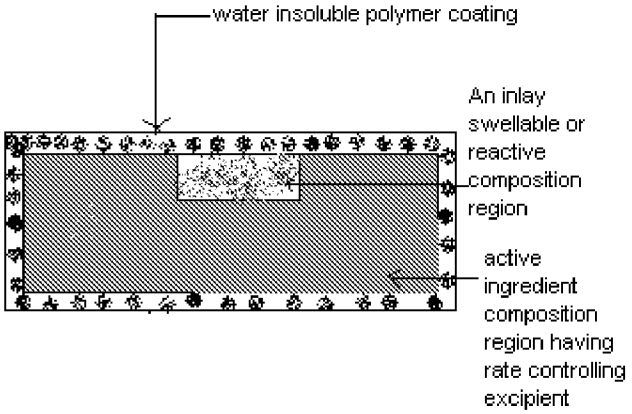
System as claimed in claims 25 and 42 after contact with aqueous environment



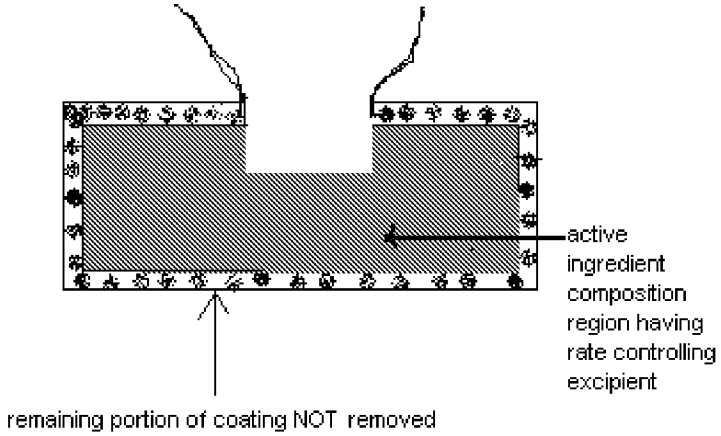
Applicants' orally administerable drug delivery system having an in-lay as presently claimed in dependent claim 40 is illustrated in the following figures.

Upon contact with aqueous environment, at least one preselected portion of the coating is removed, and water enters into the swellable or reactive composition where it causes the swellable region to swell or the reactive region to react, and "blow off" only that portion of the insoluble polymer layer in contact with the swellable or reactive composition. As a result, as shown below, only the core portion of Applicants' orally administerable drug delivery system remains.

System as claimed in claim 40 before contact with an aqueous environment.



System as claimed in claim 40 after contact with aqueous environment.



Rejection of Claims Under 35 U.S.C. § 103

Claims 25-31, 34-40, and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of Conte et al. (USPN 6,294,200 hereafter '200) in view of Hayashida et al. (USPN 5,593,694 hereafter '694). Applicants respectfully traverse this rejection.

The Office Action states,

> "The '200 patent teaches a coated tablet comprising a core and a coating (abstract). The core comprises layers (Figures), comprising an active pharmaceutical component comprising excipients (col. 4, lin. 55-65; col. 7, lin. 53-col. 8, lin. 26) and a swelling components (col. 5, lin. 29-40). The swellable components comprise swellable components like cellulose wicking agents, osmogents like lactose, (col. 5, lin. 10-25). The formulation comprises a second active ingredient that is released in an immediate release form (part 5, col. 3, lin. 60-65). The coating surrounds the core layers with the swellable layer in contact with the coating (part 2, Figure 3). The swellable components are present as an in-lay tablet layer surrounded by the coating (Figures). Upon release the immediate release portion is removed and exposes the core layers. The coating polymer is impermeable to the drug composition comprising cellulose phthalates (col. 6, lin. 25-45). The removed immediate release coating acts as a passageway on the coating for the active agent to be released. The formulation is further coated with a pH dependent coating (col. 7, lin. 10-20)."

The office action further states:

> "The '200 patent discloses an orally administerable drug delivery system comprising a core and a coating. The coating surrounds the core, where the core comprises active regions. The coating has a region operable to be removed while the remaining coating does not dissolve."

The Office Action admits that the '200 patent fails to disclose the use of a semipermeable coating and relies on Hayashida '694 for this feature.

The Office Action then argues that,

> "The '694 patent teaches an oral administrable drug delivery system comprising a core and a coating (abstract). The core comprises an active ingredient along with an excipient (col. 5, lin. 60-col. 6, lin. 65). The core tablet further comprises swellable portions (col. 4, lin. 34-60). The core is surrounded by a coating that is in immediate vicinity of the drug and swellable portions. The periphery of the coated tablet is thinner than the top and bottom and upon administration will absorb water (col. 4, lin.

> 12-34). The coating is semipermeable to water around the edges (col. 7, lin. 10-20). The water absorption activates the water swellable portions of the core tablet forcing release of the active agent, while the top and bottom portions of the coating remain intact (Figures 2A, 2B). The sides of the coating are preselected to be removed after contact with the aqueous environment of the body, while the top and bottom portions are not removed (Ibid.) Since the tops and bottom of the dosage form does not dissolve or transmit drug to the aqueous environment, the side act as passageways for the drug to move through. The swellable agents include cellulose wicking agents, and osmogents such as lactose (col. 5, lin. 60-65). The dosage form is capable of zero-order release of the active agents (col. 7, lin. 30-35). The solid core tablet is a compressed tablet comprising a single layer of the components comprising both the active ingredient components and the swellable composition (Examples).

The Office Action concludes that it would have been obvious to include the semipermeable polymer combination [of the '694 patent] to the coating of the '200 formulation in order to provide a more precise release of the drug core.

Applicants respectfully disagree with the Examiner's interpretation of the '200 patent, particularly with regard to the assertion that "The coating surrounds the core layers with the swellable layer in contact with the coating (part **2**, Figure 3)." The Examiner's attention is directed to Figures 3 and 4 of the '200 patent reproduced below for the Examiner's convenience (comments added).

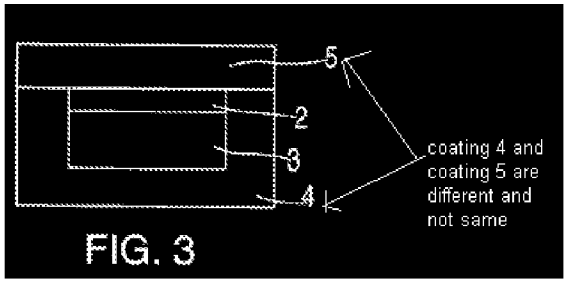


FIG. 3

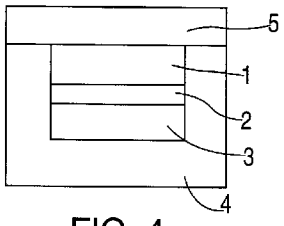


FIG. 4

Figures 3 and 4 of the '200 patent teach a layered core having two different coatings (part **4** and part **5**), each only partially covering a portion of the core, each having a different function and a different composition. Part **4** is a water impermeable coating that only partially covers a portion the core on the lower and lateral surfaces. (*See*, column 3, lines 47-48; and column 6, lines 15-21). Part **5** is a soluble coating that "is characterized by having a composition able to allow for the fast release of the active substance itself." (*See,* column 3, lines 62-65). This

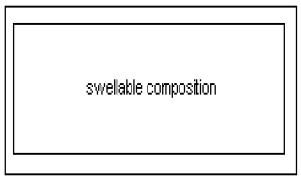
distinction is further elaborated upon, "This core is coated by compression, on the upper part by a fast disintegration and dissolution coating **5** containing an active substance quantity which is quickly released and on the lateral surface of layer **2** whereas on the lateral and lower surface of layer **3** by the coating **4** which forms a barrier impermeable for a specified period of time." (*See*, column 4, lines 33-37; emphasis added.) Thus, in the '200 patent, the coating **4** comprising a water-insoluble polymer component and a water leachable component only partially covers the core and does not completely surround the core with the same coating material.

In contrast, Applicants' coating (Applicants' part **2**) as presently recited in Applicants' independent claims 25 and 42 ± comprises a water-insoluble polymer coating that surrounds the core with the same coating material. It is a single coating, not two different coatings as in the '200 patent. This feature is contrary to what is taught in the '200 patent.

The addition of Hayashida (the '694 patent) does not cure the deficiencies of the '200 patent. Hayashida is cited to show a semipermeable polymer completely surrounding the core.

In contrast to Applicants' claimed invention, the sustained release tablet of the '694 patent teaches "a sustained release tablet comprising a single region base tablet containing a water-swellable gelling agent and a pharmaceutically active ingredient dispersed homogeneously in said gelling agent, said single region base tablet being coated with a film coating composition prepared by dissolving one or two members from ethylcellulose and acetylcellulose in an organic solvent." (*See,* column 3, lines 26-32; emphasis added).

In addition, the construction of the sustained release tablet disclosed in the '694 patent is illustrated by following figure:



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While the tablet coating of the '694 patent is said to have a central band that preferentially dissolves, it does not have a preselected portion which is removed and a remaining portion which is not removed. As shown below in Figures 2A and 2B of the '694 patent the

central band randomly swells or dissolves in a shell shape (Fig. 2A) or in a lantern shape (Fig. 2B) leading to release of the active ingredient. (See, the '694 patent, column 3, lines 40-43). This is because the water-swellable gelling agent and a pharmaceutically active ingredient are dispersed homogeneously in said gelling agent.

FIG. 2A

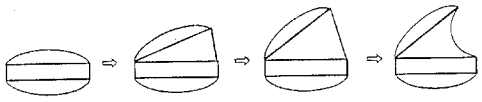
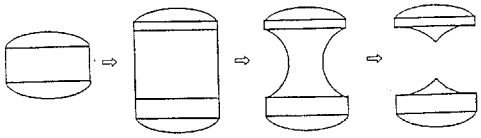


FIG. 2B



Applicants assert that the uncertainty as to how the tablet of the '694 patent swells or dissolves cannot be interpreted as "a preselected portion" as presently recited in Applicants' claims 25 and 42:

> "...at least one swellable or reactive composition layer is located in an immediate vicinity of one or more preselected portions of the coating in order to be in communication with said preselected portions of the coating; and the at least one active ingredient composition layer is in vicinity of another portion of the coating; and
>
> wherein at least one preselected portion of the coating is removed after contact with an aqueous environment and wherein the remaining portion of the coating is not removed"

Even in the wake of *KSR v. Teleflex* 82 USPQ2d 1385 (U.S. 2007), in order for a combination of references to render an invention obvious, it must be apparent that their teachings can be successfully combined. *In re Avery* (CCPA 1975) 518 F2d 1228, 186 USPQ 161. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teachings, suggestion or incentive supporting the combination. *In re Geiger* (CAFC 1987) 815 F2d 686, 2 PQ2d 1276; *In re Fine* (CAFC 1988) 837 F2d 1071,

5 PQ2d 1596. The mere fact that references can be combined does not render the resultant combination obvious unless the prior art and/or the "common sense" of the person of ordinary skill also suggests the desirability of the combination. *Berghauser v. Dann. Comr. Pats.* (DCDC 1979) 204 USPQ 393; *ACS Hospital Systems, Inc. v. Montefiore Hospital* (CAFC 1984) 732 F2d 1572, 221 USPQ 929.

Applicants' oral drug delivery system is not obvious over the combination of the '200 and '694 patents because of Applicants' unique construction of a coating completely surrounding a core having two separate regions. The '200 patent fails to teach or disclose a tablet having a single coating surrounding a core. The '694 patent fails to teach or disclose a tablet having two separate regions – an active ingredient composition region, and a swellable or reactive composition region. Nothing in the either the '200 patent or the '694 patent either alone or taken together suggests such a combination.

Applicants' distinct separate regions allows pre-selection of the one or more portions of the surface from where the coating is removed partially or fully, when the system comes in contact with an aqueous environment. Thus, there are one or more definite preselected surfaces from where the coating gets removed. The coating in the vicinity of the active ingredient composition region, which is the remaining portion of the coating, is not removed.

In essence, the Office Action combines the water permeable coating disclosed in the '694 patent with the layered construction disclosed in the '200 patent. Applicants assert that to do so would involve conceiving or conceptualizing multiple steps:

1. Selectively choose from embodiments given in Figures 1 to 4, only the embodiment of Figure 3 of the '200 patent.
2. To further selectively choose only parts **2** and **3** of Figure 3 of the '200 patent to construct applicant's claimed invention. In other words, conceive or conceptualize the removal of the water impermeable coating (part **4** of the '200 patent) as well as the water soluble coating (part 5 of the '200 patent) that may also contain the active substance. Applicants assert that conceptualizing the removal of the water soluble coating (part **5** of the '200 patent) would remove an essential embodiment recited in the claims of the '200 patent – the upper layer may consist of an active substance. (See, claim 1 of the '200 patent).

3. Conceptualizing the replacement of the removed coatings (parts **4** and **5**) of the '200 patent with the water permeable coating of the '694 patent. Applicants further assert that this would defeat yet another essential embodiment recited in the claims of the '200 patent – release of the active ingredients at with a time interval between their release. (See, claim 1 of the '200 patent).

Applicants' assert that one skilled in the art of pharmaceutical tablet manufacture would not conceptualize the removal of the two coatings from the '200 patent and replace them with the water permeable coating of the '694 patent into the construction of the '200 patent because it would defeat essential embodiments recited in the claims of the '200 patent.

Applicants believe that a fair reading of the '200 and '694 patents, either alone or in combination, provides no teaching, suggestion, or motivation for one skilled in the art to prepare a tablet having a single coating surrounding a core having two separate regions: an active ingredient composition region, and a swellable or reactive composition region into Applicants' tablet as presently claimed.

In view of the above amendments and remarks Applicants believe that claims 25-31, 34-40, and 42 are now patentable. Withdrawal of this rejection and allowance of claims 25-31, 34-40, and 42 is respectfully requested.

Claims 25-31, 34-40, and 42 are patentable at least for the reason that the Examiner has engaged in impermissible hindsight reasoning.

Applicant respectfully notes that engaging in hindsight reconstruction is impermissible. "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.[1]" It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.[2]

[1] *In re Fine*, 5 USPQ2d at 1600.
[2] *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391,393 (CCPA 1965).

As discussed above, Applicants assert that there is no suggestion in either the '200 or '694 patents, alone or in any combination to prepare an orally administerable drug delivery system comprising at least one preselected portion of the coating that is adjacent to a swellable or reactive region is removed while leaving the remaining portion intact – except by using Applicants' invention as a template through a hindsight reconstruction of Applicants' claims.[3] Similarly, the Examiner has not identified any preexisting need or problem to be solved that might prompt one of skill in the art to combine the references. In essence, the Examiner's reasoning lacks any articulation as to why one would initially think of combining the features from the references to arrive at the claimed invention.

The Examiner's comments are highly suggestive that the Examiner is using Applicants' structure as a template and selecting individual elements from each of the '200 and '694 references in a mere hindsight reconstruction of Applicants' claimed invention. Applicants assert that the Examiner is merely considering whether the differences between selected features of Appellant's claims and the references are obvious, not whether the invention as a whole is obvious. The U.S. Supreme Court has held that USPTO personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered.[4] When considered as a whole, Applicant's claimed elements are neither taught nor suggested by any combination of the '200 or '600 patents.

For these additional reasons Applicants assert that claims claims 25-31, 34-40, and 42 are patentable over the '200 and '694 patents. The cited references considered alone or in combination, do not render the claims obvious and that the claims are patentable over the cited art and therefore fail to support the *prima facie* case of obviousness presented in relation to Applicants' claims 25-31, 34-40, and 42.

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[3] *Ex Parte Crawford et al,* Appeal 20062429, Decided May 30, 2007.

[4] *See, e.g., Diamond v. Diehr*, 450 U.S. 175, 188-89, 209 USPQ 1, 9 (1981).

CONCLUSION

Applicants respectfully submit that all claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' representative at (612) 373-6961 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date June 17, 2011

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